AMENDMENTS IN THE DRAWINGS

Attached please find replacement drawing sheets 1, 7, 8 and 9 to substitute the corresponding original sheets filed in compliance with 37 CFR Sec. 1.84.

ARGUMENTS/REMARKS

Claims 1–27 were pending in the application. Claims 1 - 27 have now been canceled and replaced by new claims 28 – 56, to better define the scope of the invention. Claims 28, 41, 47, 51 and 53 are independent.

In the present response, Applicant is filing a corrected Oath herewith.

In the office action, the drawings were objected to for a number of informalities. In response, Applicant has prepared the attached Replacement Sheets for Figs. 1A, 1B, 7A, 7B, 7D and 8A. In the Replacement sheets:

Figures 1A and 1B have been amended to include the label "Prior Art".

Figures 7A, 7B, 7D and 8A have been amended to replace the handwritten characters by typed characters. Reconsideration and withdrawal of the objections are respectfully requested.

In the office action, the specification was objected to as containing a number of informalities, as listed on page 4 of the Office Action. In response, the Applicant has prepared a substitute specification, as attached herewith, and a marked-up copy version showing the amendments made. In the substitute specification, no new matter has been added. The specification has been amended to correct grammatical errors and to remove inconsistent terminology for designated characters. The specification was further amended by capitalizing Venturi throughout the specification and by adding a period at the bottom of page 8.

In the office action, claims 1 – 27 were objected to for lacking proper antecedent basis for the limitations following the terms 'the' and 'said' that are used in the claims. Claims 1 – 27 were further objected to for not being consistent in the capitalization of Venturi. The objections to the claims 1 - 27 have been rendered moot in view of the

cancellation of the claims. Applicant respectfully requests that these objections be withdrawn.

In the office action, claims 12, 13 and 27 were rejected under 35 USC §101 as reciting use without setting forth any steps dellimiting how this use is actually practiced. Clams 12 and 13 have now been rephased to overcome this objection. The rejections of claims 12, 13 and 27 have been rendered moot in view of the cancellation of these claims. Applicant respectfully requests that these rejections be withdrawn.

In the Office Action, claims were rejected under 35 USC §112 as being confusing because the claim recites the phrase 'a low cross-section flexible tubing'.

Claims 12, 13 and 27 were rejected as reciting use without setting forth any steps delimiting how this use is actually practiced.

Claims 14 and 19 were rejected as being confusing because of redundancy.

Claim 21 was rejected as being confusing because the claim recites the phrase 'to the user head'.

Claim 22 was rejected as being confusing because the claim recites the phrase 'the Venturi devic is having an end open ...'.

The rejections of claims 12, 13, 14, 19, 21, 22 and 27 have been rendered moot in view of the cancellation of these claims. Applicant respectfully requests that these rejections be withdrawn.

In the office action, claims 1-10, 12-20 and 22-27 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 10/565,363. U.S. This rejection is rendered moot because claims 1 through 27 have been canceled by the present amendment. Any terminal disclaimer that may be required will be considered after allowance of the pending claims over the prior art of record. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In the office action, claims 1-2, 4-5, 7, 11-13, 15-17 and 22-27 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sherrod (US 5,979,444).

Claim 3 was rejected under U.S.C. § 103(a) as being unpatentable over Sherrod in view of Hill et al. (US 2002/0096174)

Claims 6, 8-10 and 18 were rejected under U.S.C. § 103(a) as being unpatentable over Sherrod in view of Boussignac (US 6,363,935).

Claims 14, 19 and 21 were rejected under U.S.C. § 103(a) as being unpatentable over Sherrod in view of Moa et al. (5,193,532) taken together with Trimble et al. (US 4,782,832).

Claim 20 was rejected under U.S.C. § 103(a) as being unpatentable over Sherrod in view of Moa et al. taken together with Goldstein (US 5,752,510).

Applicant has now submitted a new set of claims 28 – 56 to claim the full scope of the present invention.

The present invention provides a respiratory aid system and method which are particularly aimed at minimizing discomfort to people suffering from sleep apnea (see for example page 9, lines 12 -21). Unlike artificial respiratory systems that are used under emergency situations or in hospitalization settings, respiratory aid systems which are intended for use by people suffering from sleep apnea and are used in daily life settings by people who conduct normal life. Thus, it is particularly important for such systems to be as comfortable and easy to operate as possible. It is also preferable for such systems to be portable and capable of operating independently of electric power lines in order to allow the user to use the apparatus when sleeping away from home, as for example during long night travel or camping.

In accordance with the claimed present invention, the aforementioned aims are achieved by incorporating a Venturi device into an air delivery nasal interface and utilizing a flow of high pressure air that enters the nasal interface through the Venturi device as a driving force for drawing ambient air into the interface. Most of the air

supplied to the user originates not from the source of high pressurized air, but from the atmosphere. By having most of the air supplied from the atmosphere, the volume capacity demands required from the source of the high pressure air are significantly reduced. Further, the use of a portable container of compressed air for extended periods of time or a low capacity air compressor are permitted. It further allows for use of thin tubing and a small nasal interface to further enhance comfort of use.

By further incorporating a breathing sensor into the nasal interface, the efficiency of the device as well as the user's comfort are further enhanced by allowing the system to function according to the real-time physiological needs of the user and/or to operate intermittently so as to supply positive pressure only during the inhalation phase (page 13 lines 3-12). In this respect, it should also be emphasized that due to the high pressure delivered to the nasal interface, the response of the system is instantaneous (page 13 lines 3 -7) because of the narrow tubing that maintains the high pressure of the air entering the Venturi device(s). Thus, the present invention provides a complete feed-back system and method for the measured regulation of the supply of air to sleep apnea patients.

Applicant respectfully submits that none of the cited documents teaches the present invention as recited in the new set of claims, either alone or in combination.

Independent claim 28 is directed to a portable respiratory aid system for administrating a regulated flow of air to a person's airway, especially to a person suffering from sleep apnea. The respiratory aid system has a source of high pressure air and an air delivery nasal interface. The nasal air delivery interface includes at least one nasal adaptor having an air passage and being attachable to a person's nostril. The system further includes at least one Venturi device having a central space, a first and a second open ends, and a first inlet which opens into said central space. The first open end is open to surrounding ambient air and the second open end is in fluid communication with the air passage of the at least one nasal adaptor. The first inlet is configured for receiving a flow of high pressure gas and for directing the flow of high pressure gas toward the

second open end. The system further has at least one sensor for monitoring breathing of the person and at least one flexible thin tubing connecting the source of high pressure air and the first inlet of the at least one Venturi device for delivering a flow of high pressure air from the source of high pressure air to the first inlet of the Venturi device. The system further has a control unit operably connected to the sensor for regulating said flow of high pressure air in accordance with the monitored breathing.

Independent claim 41 is directed to an air delivery nasal interface. Claim 41 provides for at least one nasal adaptor attachable to a person's nostril, with the at least one nasal adaptor having an air passage and at least one Venturi device. The at least one Venturi device has a central space, first and second open ends, and a first inlet which opens into the central space. The first open end is open to surrounding ambient air and the second open end is in fluid communication with the air passage of the at least one nasal adaptor. The first inlet is configured for receiving a flow of high pressure gas and for directing the flow of the high pressure gas toward the second open end. At least one sensor for monitoring breathing of a person using the nasal air delivery unit is also provided.

Independent claim 47 is directed to an air delivery nasal interface. Claim 47 provides for two air delivering units for delivering a flow of air to one of a person's nostrils. Each of the two air delivery units has a nasal adaptor, having an air passage, and is attachable to a person's nostril. Claim 47 further provides for a Venturi device having a central space, a first and a second open ends, and a first inlet which opens into the central space. The first open end is open to surround ambient air and the second open end is connected to the air passage of the nasal adaptor. The first inlet is configured to receive a flow of high pressure respiratory gas and to direct the flow of high pressure respiratory gas toward second open end. Claim 47 further provides for at least one sensor for monitoring breathing of a person using the nasal air delivery unit.

Independent claim 51 is directed to an air delivery nasal interface. Claim 51 provides for two Venturi devices pivotally mounted on opposite ends of a flat flexible member configured to be placed between mouth and nose. Each of the two Venturi devices has a hollow member defining a central space. The hollow member has a first and a second open end; a first inlet connectable to a thin tubing which opens into the central space. The first open end is open to surround ambient air and the second open end is provided with a nasal adaptor configured to be attached to a person's nostril. The first inlet is configured to receive a flow of high pressure respiratory gas via the thin tubing and to direct the flow of high pressure respiratory gas toward the second open end.

Independent claim 53 is directed to a method for administrating a controlled flow of air to a person suffering from sleep apnea, in accordance with the real-time needs of the person. Claim 53 provides for connecting a portable source of compressed air by means of a thin tubing to an inlet port of an air delivery nasal interface. The air delivery nasal interface includes at least one Venturi device interposed between inlet port and at least one nasal adaptor configured to be attached to a person's nostril. The at least one Venturi device has a first open end which opens to ambient air and a second open end which opens into an air passage in the nasal adaptor. Claim 53 further provides for monitoring the breathing of person; delivering a flow of compressed air from the source of compressed air via the thin tubing to the air delivery nasal interface; and regulating the flow of air in accordance with the monitored breathing.

The Sherrod patent teaches a device for providing oxygen to a non-breathing person as part of a cardiopulmonary resuscitation (CPR) which further provides for evacuating air during exhalation phase. The device includes a face mask to be placed over the mouth of the patient, an oxygen dispenser and a conveying piece which alternately injects oxygen into the mask during inhalation phase and withdraws air from the patient's mouth during exhalation phase. Thus, the present aid respiratory system as recited in new claim 28, differs from the Sherrod patent device both structure and function. First, Sherrod does not teach a small nasal interface but rather, a face mask.

Second, Sherrod does not teach that the device includes a sensor for monitoring the patient's breathing, nor a control unit for regulating the flow of high pressure air delivered to the user respiratory interface in accordance with the monitored breathing. Finally, it should also be mentioned that according to Sherrod, the high pressurized gas delivered to the respiratory interface is oxygen, not air as in the present system.

In the Office Action, page 14, fourth paragraph, the Examiner asserts that it would be obvious to modify the Sherrod patent device by forming a compact dual breathing channel as taught by Moa et al. and using nostril adaptors as taught by Trimble et al., to form a compact, comfortably worn device that administrates air to each respective nostril of a patient. As mentioned above, Sherrod's device is especially designed for providing artificial respiration to a non-breathing person as part of a CPR procedure. Accordingly, Sherrod teaches a face mask to be placed over the patient's mouth as clearly depicted in Fig. 3 and explicitly disclosed in col. 3, lines 20-24. In col. 3 lines 47-60, Sherrod further emphasizes that the mask must be placed over the patient's mouth and must perform the same functions as those described in association with Fig. 3. Thus, Applicant respectfully submits that indeed Sherrod teaches away from using an air delivery nasal interface.

In the third and fourth paragraphs on page 13 of the Office Action, the Examiner asserts that Boussignac teaches a Venturi device with a pressure sensor for detecting overpressure and that therefore it would be obvious to modify Sherrod's respiratory aid apparatus by using the pressure sensor in order to prevent overpressure. In the presently presented new claim 28, the sensor monitors the patient's breathing, and the control unit controls the flow of high pressure air delivered to the air delivery nasal interface in accordance with the monitored breathing. Thus, in accordance with the claimed present invention, the sensor is not necessarily a pressure sensor but may be any sensor capable of monitoring breathing such as sound transducer, a temperature detector or a chest-mounted detector as claimed in new claims 32 and 39. Applicant would like to emphasize that, as explained above, the combination of a sensor and a control unit as taught by the claimed present invention, allows for regulating the flow delivered to the

user in accordance with the real–time needs of the user. Thus, during periods of regular breathing, the supply of positive pressure can be turned off completely, while upon detection of a breathing disorder, for example by detecting a cessation of breath or a significant change in the breath periodicity, the positive pressure is turned on (page 14 lines 3 -6). Neither Sherrod nor Boussignac teach these features.

Finally, with respect to claim 28, both Sherrod and Boussignac relate to artificial respiratory systems that are used either under emergency or in hospitalization settings and are designed to be operated by a user treating the patient and obviously not by the patient himself. This is very different from system claimed in claim 28 which is respiratory system especially designed for people suffering from sleep apnea.

Applicant respectfully submits that none of the cited documents teaches an air delivery nasal interface having the limitations recited in claims 41, 47 and 51. In particular, none of the cited documents teaches an air delivery nasal interface comprising at least one Venturi device and a sensor for monitoring breathing, as claimed in claim 41, or two Venturi devices, each for each respective nostril of the user and a sensor for monitoring breathing, as claimed in claims 47 and 51.

In the Office Action, three patents have been cited in relation to an air delivery nasal interface: Moa et al., Trimble et al. and Goldstein. Applicant respectfully submits that both Trimble et al. and Goldstein generally teach a nasal interface but do not disclose a Venturi device or a sensor for monitoring breathing. Further, as can be clearly seen in the drawings, the inlet port of the nasal interfaces disclosed by these two patents, are connected to a regular wide-bore hose and not to thin tubing as taught by the claimed present invention.

The Moa et al. patent teaches an air delivery nasal interface for delivering a constant stream of air/respiratory gas to a patient with impaired pulmonary function, the main purpose of which is to supply air at a constant pressure throughout the breathing

cycle (col. 1, lines 28 – 31 and lines 36 – 40). Thus, the Moa et al. patent does not teach a sensor for monitoring breathing for allowing self-regulation of the air supply according to the requirements of the patient. Further, the Moa et al. patent does not teach a bi-directional Venturi device as claimed in new claims 45 and 50.

Further with regard to claim 53, Applicant respectfully submits that none of the cited document teaches a method for administrating a controlled flow of air to a person suffering from sleep apnea. In particular, none of the cited documents teaches the steps of monitoring the breathing and regulating the flow of air in accordance with monitored breathing, as recited above in association with claim 28.

Applicant believes that the application is now in order for allowance. Accordingly a notice of allowance for all the claims is respectfully requested.

Respectfully submitted,

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